IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

GOOSE CREEK PHYSICAL MEDICINE, LLC, Plaintiff, vs. XAVIER BECERRA, *in his official capacity as Secretary, United States Department of Health and Human Services*, Defendant.	No. 2:22-cv-03932-DCN **ORDER**

The following matter is before the court on defendant Xavier Becerra's (the "Secretary" or "Secretary Becerra") motion for reconsideration, ECF No. 73, of the court's order, ECF No. 66, granting plaintiff Goose Creek Physical Medicine, LLC's ("GCPM") motion for sanctions, ECF No. 53. For the reasons set forth below, the court denies the motion for reconsideration.

I. BACKGROUND

A. The Medicare Act

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq., commonly known as the Medicare Act, established a system of governmentally funded health insurance for elderly and disabled persons.[1] Under the Medicare Act, certain healthcare providers are eligible for reimbursement by the Department of Health and Human Services ("HHS") for services furnished to the Medicare beneficiaries. To promote the

[1] The court notes that the remaining facts included in this section are drawn from the amended complaint unless otherwise specified, and therefore, the court omits citations throughout. See ECF No. 24, Amend. Compl.

integrity of the Medicare program, the Secretary of HHS is authorized to enter into contracts with private entities to review claims for reimbursement submitted by providers; to determine whether Medicare payments should not be, or should not have been, made; and to recoup payments that should not have been made. See 42 U.S.C. § 1395ddd; 42 C.F.R. § 405.371(a)(3).

As this court noted in its most recent order in this case, ECF No. 66, there is a barrage of acronyms included within the amended complaint and subsequent briefs. Therefore, the court finds it helpful to define the most salient acronyms and to review the Medicare claims appeal process, despite the apparent redundancy with its previous order. In so doing, the court attempts to summarize the Medicare claim appeal process that precedes the filing of a complaint in federal court, before turning to the facts of the operative complaint.

There are several levels of agency review before judicial review of a Medicare denial is permitted. First, the Centers for Medicare and Medicaid Services ("CMS"), an agency of HHS, administers the Medicare program and directs its contractors, who are responsible for the first two levels of administrative review of Medicare denials. Second, CMS contracts with Medicare Administrative Contractors ("MACs") to process and audit claims that have been submitted by Medicare providers in a specific geographic area of the country. MACs handle provider and supplier enrollment, as well as redeterminations, which form the first level of the Medicare claims appeal process. Third, until 2016, Zone Program Integrity Contractors ("ZPICs") audited the payment decisions made by MACs in a process referred to as a "post-payment review," which identified both overpayments and underpayments. In fiscal year 2016, CMS began transitioning from ZPICs to Unified

Program Integrity Contractors ("UPICs"), which now perform similar duties to what ZPICs previously performed.

Fourth, CMS is mandated to enter into contracts with qualified independent contractors ("QICs") to conduct reconsiderations of redetermination decisions. The QICs are statutorily required to be independent of any MAC, ZPIC, or UPIC, as the QICs form the second level of the Medicare claims appeal process. The Office of Medicare Hearings and Appeals ("OMHA") is responsible for the third level of the Medicare claims appeal process—whereby a reconsideration decision by the QIC is reviewed by an OMHA adjudicator—and the appellant Medicare provider may request a hearing before an administrative law judge ("ALJ"). If a party is dissatisfied with the ALJ's decision, that party may appeal the decision to the Medicare Appeals Council (the "Council"), and the Council is statutorily authorized to review the ALJ's decision. The Council is located within the Departmental Appeals Board ("DAB") of HHS and provides the fourth level of administrative review. The fifth level of appeal is judicial review in a federal district court.[2]

The CMS contractors evaluate overpayments to Medicare providers and suppliers through statistical sampling and extrapolation. CMS Ruling 86-1 was the first ruling that allowed a fiscal intermediary—such as a MAC, ZPIC, or QIC—to use sampling and extrapolation instead of claim-by-claim review. Chapter 8, Section 4, of the Medicare

[2] Given the complexity of this review process, the delays affecting the Medicare appeals process, and the lengthy and expensive cost to appeal, the court echoes a lament from the Fifth Circuit: "Are these redundant, time-consuming, and costly procedures worthwhile for program integrity or providers? One is reminded of Prof. Gilmore's aphorism: 'In Hell there will be due process, and it will be meticulously observed.'" Maxmed Healthcare, Inc. v. Price, 860 F.3d 335, 344–45 (5th Cir. 2017) (quoting Grant Gilmore, The Ages of American Law 111 (Yale 1977)).

Program Integrity Manual ("MPIM") provides detailed requirements for CMS contractors to follow in developing an audit plan and executing the sampling and extrapolation process. Ctrs. for Medicare & Medicaid Servs., Pub. 100-8, MPIM § 8.[3] Under § 8.4.1.3 of the MPIM applicable during the statistical sampling and extrapolation at issue, the six mandatory steps were:

> (1) Selecting the provider or supplier;
> (2) Selecting the period to be reviewed;
> (3) Defining the universe, the sampling unit, and the sampling frame;
> (4) Designing the sampling plan and selecting the sample;
> (5) Reviewing each of the sampling units and determining if there was an overpayment or an underpayment; and, as applicable,
> (6) Estimating the overpayment.

Id. § 8.4.1.3; see also Amend. Compl. ¶ 169. At the time of the underlying analysis, the MPIM defined the "universe" and the "sampling frame" to "usually cover all relevant claims or line items for the period under review." MPIM § 8.4.3.2. For purposes of extrapolation, the "target universe" of a provider's Medicare claims consists of "fully and partially paid claims" submitted by the provider within the chosen time period. Id. § 8.4.3.2.1.B.

Once the "sampling unit"[4] is selected, the relevant limiting criteria are applied to the target universe, and the resulting set of sampling unit data is called the "sampling

[3] The court notes that the cited Chapter 8 of the MPIM in effect at the time of the underlying analysis has been archived within the agency's website but is available at the following link. Ctrs. for Medicare & Medicaid Servs., Pub. 100-8, MPIM § 8 (enacted May 27, 2011), https://perma.cc/MU2A-F4XC. When the court cites to the MPIM throughout this order, it is citing to the MPIM adopted on May 27, 2011, which was still in effect at the time of the sampling and extrapolation at issue.

[4] The sampling unit is the information that the contractor wishes to measure. The operative MPIM for this case indicates that its summary assumes that the sampling unit is the claim, although this is not required. MPIM § 8.4.3.2. The sampling unit may also be "a cluster of claims, as, for example, the patient, a treatment 'day', or any other sampling unit appropriate for the issue under review." Id. "Sampling units are the elements that

frame."[5] The contractor then takes a random selection of the claims in the sampling frame, and the contractor's medical review staff audits each claim in that sample to determine whether the claim was properly paid, overpaid, underpaid, or improperly denied payment. See generally MPIM § 8.4.4. Upon completing review of the claims sampled from the "sampling frame," the contractor calculates the net average amount by which the provider was incorrectly paid for the sampled claims. In cases where the provider was initially overpaid, the net overpayment identified in the sample is then projected to the sampling frame of that provider's claims to form the extrapolated overpayment amount. This process requires the contractor to accurately assess underpayments as well as overpayments, including claims that were unpaid after adjudication ("zero-paid claims")[6] to ensure the actual net overpayment is correctly calculated. Should a contractor seek to recover an overpayment from a provider, the contractor should include information about the review and statistical sampling methodology that was followed in the overpayment demand letter.

B. Procedural History of this Dispute

GCPM is a South Carolina limited liability company and a former for-profit provider of physical medicine services, including chiropractic services, which was

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are selected according to the design of the survey and the chosen method of statistical sampling." Id. § 8.4.3.2.2.

[5] "The sampling frame is the 'listing' of all the possible sampling units from which the sample is selected." MPIM § 8.4.3.2.3. "The ideal frame is a list that covers the target universe completely." Id.

[6] Zero-paid claims, which are claims that were unpaid after adjudication, are distinguishable from unpaid claims, which are claims that have been submitted for payment but have not yet been adjudicated or processed for payment determination.

enrolled as a provider of services in the Medicare program.[7] GCPM filed a complaint for judicial review against Secretary Becerra, in his official capacity as the Secretary of HHS. GCPM alleges violations of law in the design and execution of the statistical sampling and the calculation of the alleged overpayment amount, plus interest, on claims GCPM submitted to Medicare. It also alleges improper accounting on payments made on the alleged overpayment. The relevant period is for dates of service between March 5, 2011, and November 30, 2013. The complaint appeals the final decision of the Secretary and brings related statutory and constitutional claims.

GCPM purportedly failed an audit performed by CMS's designated ZPIC: NCI AdvanceMed ("AdvanceMed"). AdvanceMed opened an investigation into GCPM's claims based on data analysis that GCPM's top-billed code, other than for evaluation and management services, was for CPT[8] 64450, a nerve block procedure. On October 14, 2014, AdvanceMed sent GCPM its Post-Payment Review Results and Overpayment Extrapolation Report ("OER") containing the results of its completed audit. The report identified that AdvanceMed used a form of stratified statistical sampling to select 67 claims and 210 CPT line items from a total 2,979 claims and/or line items.[9] AdvanceMed explained that it initially identified an error rate of 89.5%; however, it

[7] As of September 2017, GCPM's clinic ceased operations. However, GCPM's limited liability company remains in existence and is in good standing with the state of South Carolina.

[8] The current procedural terminology ("CPT") codes offer doctors and health care professionals a uniform language for coding medical services and procedures.

[9] Somewhat confusingly, CMS uses the language "sampling units" to identify the claims included in the target universe but also uses the terminology "sampling unit" to define the criteria employed to identify the sampling frame from the target universe. See, e.g., MPIM § 8.4.3.2.2; supra n.4. To avoid this confusion, the court will simply refer to the "sampling units" by identifying them as the claims and/or line items included in the target universe.

voided sixteen zero-paid claim lines, "as they constitute no loss to the Medicare Trust Fund," which ultimately increased the error rate to 94%. Amend. Compl. ¶ 207. "AdvanceMed then extrapolated the 94% error rate across the frame of 'all codes billed' from the Review Period," to determine an overpayment amount of $337,693.09. Amend. Compl. ¶ 208 (citing Admin. R. 1 at 521). AdvanceMed purportedly sent GPCM an encrypted CD as well as the OER, but the information provided "did not contain the actual universe of claims on which the overpayment was determined." Id. ¶ 210. On November 26, 2014, CMS's designated MAC for South Carolina, Palmetto GBA, LLC ("Palmetto"), formally issued a demand for repayment in the amount of $337,693.09.

Four levels of administrative review have since followed, through which GCPM challenged the validity of AdvanceMed's sampling and extrapolation conducted during the audit. First, on January 9, 2015, GCPM timely submitted a request for redetermination to the MAC. On February 13, 2015, Palmetto issued a fully unfavorable redetermination decision that confirmed the overpayment to be $343,744.24, which included the original, alleged overpayment amount plus interest. Second, on April 13, 2015, GCPM timely submitted a request for reconsideration to the QIC in response to Palmetto's unfavorable redetermination. On June 12, 2015, the reviewing QIC, C2C Solutions, Inc. ("C2C"), issued an unfavorable reconsideration decision identified as Medicare Appeal Number 1-3125869890. As of August 5, 2015, GCPM had repaid Palmetto the entire alleged overpayment amount of $355,844.92, which included the alleged overpayment amount plus interest.

Third, on August 5, 2015, GCPM timely filed a request for hearing by an ALJ with OMHA to appeal C2C's unfavorable reconsideration decision. Six years later, on

December 9, 2021, ALJ Dean Yanohira of the Phoenix Field Office held a telephonic hearing and on January 18, 2021, ALJ Yanohira issued a partially favorable notice of decision (the "ALJ Decision"). The ALJ Decision found the statistical sampling and extrapolation of overpayment to be valid but ordered that the overpayment amount be recalculated considering the partially favorable ALJ Decision. Consequently, the ALJ Decision reduced the overpayment amount to $280,018.10 and ordered that a refund totaling $60,775.79 be issued to GCPM. Fourth, on March 14, 2022, GCPM filed a Medicare Appeals Council Review Request with the Council requesting review of the ALJ Decision. GCPM specifically requested that the Council both "renew" the ALJ Decision requiring C2C to recalculate the overpayment amount and reverse the ALJ Decision regarding the validity of the sampling and extrapolation. Amend. Compl. ¶ 248.

Fifth, on June 21, 2022, GCPM electronically filed a letter with the Council, which requested escalation to federal district court if the Council was unable to timely issue a decision. On June 30, 2022, after the Council failed to timely respond within the required five-day timeframe, GCPM electronically filed its final letter with the Council stating its intent to escalate the matter to federal court by August 26, 2022, in accordance with 42 C.F.R. § 405.1132(a). On August 25, 2022, the Council issued a Notice and Order of Medical Appeals Council Granting Request for Escalation. This lawsuit followed.

On August 19, 2022, GCPM filed its complaint in the United States District Court for the District of Columbia. ECF No. 1. On October 19, 2022, that court transferred the action to the United States District Court for the District of South Carolina by consent of

the parties.[10] ECF No. 11. On March 24, 2023, GCPM filed an amended complaint, now the operative complaint, against the Secretary to allege multiple violations of GCPM's due process rights under the Fifth and Fourteenth Amendments to the United States Constitution, as well as violation of the Social Security Act, 42 U.S.C. § 1395 et seq.,[11] and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et seq. ECF No. 24, Amend. Compl.

In the time since the complaint's filing, the court has reviewed and resolved several interrelated motions. On May 17, 2024, the court granted GCPM's motion to compel completion of the administrative record, ECF No. 18, and granted Secretary Becerra's motion for protective order, ECF No. 30. ECF No. 43. Relevant in this order, the court found that GCPM had met the high bar necessary to compel completion of the administrative record and granted GCPM's motion to compel Secretary Becerra to complete the administrative record. ECF No. 43 at 25. GCPM identified that there were five files missing from the record before the court: (1) GCPM's Freedom of Information Act ("FOIA") request, (2) the Universe File, (3) the Adjusted OP File, (4) the Missing

[10] The parties agreed to transfer the case from the District Court for the District of Columbia to the District of South Carolina upon the parties' consent that venue is proper in GCPM's judicial district. ECF No. 10-1 (citing 42 U.S.C. § 405(g)). As such, the appropriate venue is the district in which the plaintiff resides or has his principal place of business. Id. GCPM's principal place of business is in the District of South Carolina and therefore the District of South Carolina is the appropriate venue for this action. Id. When a transfer is made from an improper venue to a proper one, the district court receiving the case must apply the law of the state in which it is held rather than the law of the transferor district court. 28 U.S.C. § 1406(a); Myelle v. Am. Cyanamid Co., 57 F.3d 411, 413 (4th Cir. 1995). As such, the court applies the law of this district and of the Fourth Circuit.

[11] GCPM stipulates that this court has jurisdiction over this action pursuant to 42 U.S.C. § 405(g) as applied to Medicare appeals by 42 U.S.C. § 1395ff, which authorizes judicial review of a final agency decision of the Secretary.

Universe File, and (5) the Adjusted OP File Calculations.[12] ECF No. 43 at 14–17, 24. Through GCPM's FOIA request, GCPM—and subsequently the court—received the Universe File and the Adjusted OP File, which it thereafter incorporated into the administrative record. Id. The court ordered the Secretary to produce the Missing Universe File and the Adjusted OP File Calculations within forty-five (45) days. Id. The court filed the order on March 5, 2024, meaning the Secretary had until May 7, 2024, to timely produce those files. See id. On April 19, 2024, the Secretary filed his production. ECF No. 51.

On May 17, 2024, fifty-five (55) days after the court issued its order, GCPM filed a motion for sanctions. ECF No. 53. In essence, it argued that the Secretary's production failed to include the Missing Universe File because the produced universe file omits all zero-paid claims. Id. at 1–2. In short, GCPM claims that "[Secretary Becerra] failed to preserve and produce the target universe, despite the Court's Order." Id. at 3. GCPM requested the court sanction the Secretary "in the manner it deems appropriate" and

[12] In the interests of completeness, the court summarizes each of these documents. First, GCPM's FOIA request was a FOIA request that GCPM sent to CMS requesting specific documents related to GCPM and the request for records dated January 14, 2014. ECF No. 43 at 13. While that would normally not be included in the administrative record, the court included it to explain how GCPM received the Universe File and Adjusted OP File. Id. at 25 n.15. Second, the Universe File is identified as "Attachment B – Universe.xlsx" which was a statistical methodology document that listed the fully and partially paid claim lines, but which omitted all zero-paid claims. Id. at 14. Third, the Missing Universe File is the document that includes the omitted zero-paid claims—thus, it would include all claims from the review period included in the target universe, not just the claim lines for the sampling frame. Id. Fourth, the Adjusted OP File is identified as "AdjustedOPAfterALJ.xlsx" which is a spreadsheet that purports to support Palmetto's recalculation of the overpayment amount, though it does not show the statistical analysis and related calculations that Palmetto used to reach the $60,775.79 repayment figure. Id. at 15. Fifth, the Adjusted OP File Calculations is the file that in fact demonstrates Palmetto's statistical analysis and related calculations. Id.

suggested the minimal sanction of designating the Secretary's failure to preserve and produce the target universe as an established fact for purposes of adjudicating the summary judgment motions. Id.

The court granted the motion for sanctions on August 5, 2024. ECF No. 66. In so doing, the court first considered whether the Secretary failed to obey the court's order to provide or permit discovery. Id. at 17–20. It noted that it was joining other courts that have held that a prior court order to produce or complete an administrative record could be the basis for Rule 37 sanctions. Id. at 17–18. Thereafter, the court summarized both the production that had taken place by that point and the Secretary's purported failure to produce a universe file inclusive of zero-paid claims. Id. at 18–19. The court thereafter provided definitions of terms. Id. at 19–20. The court noted that the requested file—the Missing Universe File—was not produced and that GCPM still had not received any documentation that included the target universe, inclusive of zero-paid claims. Id. Thereafter, the court evaluated whether sanctions were appropriate and, if so, what sanctions might best be tailored to the facts of this case. Id. at 21–25. The court ultimately agreed with GCPM that an appropriate sanction would be to hold, as an established fact, that both the target universe existed at the time of the initial audit and that the Secretary failed to preserve and produce this target universe.[13] ECF No. 66 at 24–25.

[13] The court provides the specific language of the imposed sanctions:

> The court holds the following two facts as established:
>
> (1) That the "target universe," defined as all adjudicated claims submitted by the provider during the period of review within the scope of the sampling unit(s), which includes "zero-paid" claims, defined as fully

On August 13, 2024, the Secretary filed a motion for reconsideration of the court's order. ECF No. 73. On August 23, 2024, GCPM responded in opposition, ECF No. 76, to which the Secretary replied on August 26, 2024, ECF No. 77. The court held a hearing on this motion on August 27, 2024. ECF No. 78. As such, the motion has been fully briefed and is now ripe for review.

II. STANDARD

A. Motion to Reconsider

Under Federal Rule of Civil Procedure 54(b), "a district court retains the power to reconsider and modify its interlocutory judgments . . . at any time prior to final judgment when such is warranted." U.S. Tobacco Coop. Inc. v. Big S. Wholesale of Va., LLC, 899 F.3d 236, 256 (4th Cir. 2018). "Rule 54(b)'s approach involves broader flexibility to revise interlocutory orders before final judgment as the litigation develops and new facts or arguments come to light." Id. "The ultimate responsibility of the federal courts, at all levels, is to reach the correct judgment under law." Am. Canoe Ass'n v. Murphy Farms, Inc., 326 F.3d 505, 515 (4th Cir. 2003). "[W]hile Rule 54(b) 'gives a district court discretion to revisit earlier rulings in the same case,' such discretion is 'subject to the caveat that where litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again.'" U.S. Tobacco

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adjudicated claims resulting in no payment to the provider, that existed at the time the audit was drawn from the Secretary's claims data; and

(2) That the Secretary, through AdvanceMed acting as the Secretary's agent within the course and scope of its contracted duties, failed to preserve and produce this "target universe."

ECF No. 66 at 24–25.

Coop. Inc., LLC, 899 F.3d at 257 (quoting Official Comm. of the Unsecured Creditors of Color Tile, Inc. v. Coopers & Lybrand, LLP, 322 F.3d 147, 167 (2d Cir. 2003)).

Accordingly, "a court may revise an interlocutory order under the same circumstances in which it may depart from the law of the case: '(1) a subsequent trial producing substantially different evidence; (2) a change in applicable law; or (3) clear error causing manifest injustice.'" Id. (quoting Carlson v. Bos. Sci. Corp., 856 F.3d 320, 325 (4th Cir. 2017)) (internal quotation marks and alteration omitted). "This standard closely resembles the standard applicable to motions to reconsider final orders pursuant to Rule 59(e), but it departs from such standard by accounting for potentially different evidence discovered during litigation as opposed to the discovery of new evidence not available at trial." Id. (internal quotation marks omitted). "[A] motion to reconsider an interlocutory order should not be used to rehash arguments the court has already considered merely because the movant is displeased with the outcome." South Carolina v. United States, 232 F. Supp. 3d 785, 793 (D.S.C. 2017). Nor should such a motion be used to raise new arguments or evidence that could have been raised previously. Id.

B. Motion for Sanctions

Federal Rule of Civil Procedure 37 permits the district court to enter orders compelling discovery and to impose an array of sanctions for the failure to comply with such orders. Fed. R. Civ. P. 37(b)(2)(A). Rule 37(b)(2)(A) governs the appropriate sanctions for failure to obey a discovery order, stating in pertinent part:

> If a party . . . fails to obey an order to provide or permit discovery . . . the court . . . may issue further just orders . . . [including] . . . dismissing the action or proceeding in whole or in part; rendering a default judgment against the disobedient party; or treating as contempt of court the failure to obey any order.

Fed. R. Civ. P. 37(b)(2)(A).

When a district court exercises its discretion to select sanctions appropriate to the particular violation, it should consider four factors:

> (1) whether the noncomplying party acted in bad faith; (2) the amount of prejudice his noncompliance caused his adversary, which necessarily includes an inquiry into the materiality of the evidence he failed to produce; (3) the need for deterrence of the particular sort of noncompliance; and (4) the effectiveness of less drastic sanctions.

McKenna v. Sovran Bank NA, 836 F.2d 546 (4th Cir. 1987) (unpublished table decision) (internal citations omitted). "A district court must consider all of these factors; however, no one factor is dispositive." Ashmore v. Allied Energy, Inc., 2016 WL 2898007, at *3 (D.S.C. May 18, 2016) (internal quotation marks and citations omitted) (quoting Elmore v. City of Greenwood, 2015 WL 3868068, at *7 (D.S.C. June 23, 2015)).

Only in limited circumstances are the drastic sanctions of dismissal and default appropriate—namely, "where the noncomplying party's conduct represents such flagrant bad faith and callous disregard for his obligations under the Rules that the sanctions are warranted not merely to prevent prejudice to his current adversary, but also to deter those who might be tempted, in the future, to engage in similar misconduct." McKenna, 836 F.2d 546. "Nevertheless, in considering what sanctions are appropriate, the court must focus on determining a sanction that fits the case at hand, considering the potential harm to the party seeking discovery and the conduct of the non-producing party." Taylor v. Specialty Mktg., Inc., 985 F.2d 553 (4th Cir. Feb. 2, 1993) (unpublished table opinion).

III. DISCUSSION

The Secretary brings its Rule 54(b) motion under the third exception—namely that the court has patently misunderstood a party or has made an error of apprehension, resulting in manifest injustice. ECF No. 73 at 2. He identifies three errors in this court's

order: (1) the order misconstrued the ALJ Decision; (2) the order's definition of a "universe" in a Medicare Part B audit turns upon the court's reference to an inapplicable provision in the MPIM; and (3) the order engaged in fact-finding and therefore deviates from the legal terms that govern a lawsuit of this nature. See id. at 2–7. The court considers each "error" in turn.

A. ALJ Decision

Upon review of the administrative record, inclusive of the ALJ Decision, the court concludes that it misstated the holding of the ALJ Decision. The ALJ Decision is the final agency decision on direct review. See Int'l Rehab. Scis. Inc. v. Sebelius, 688 F.3d 994, 1002 (9th Cir. 2012); John Balko & Assocs., Inc. v. Sec'y U.S. Dep't of Health & Hum. Servs., 555 F. App'x 188, 194 (3d Cir. 2014); see also New LifeCare Hosps. of N.C. LLC v. Azar, 466 F. Supp. 3d 124, 140 (D.D.C. 2020) ("The Court may only review a final agency action—here, the Administrator's decision. So acting as an appellate court reviewing that final action, the Court may not review what the Administrator did not." (citation omitted)). As such, the court finds it material to summarize and review the ALJ Decision. See Admin. R. 1 at 335–80.

ALJ Yanohira issued a partially favorable decision which addressed four issues. Id. at 341–42. First, he addressed whether the statistical sampling and extrapolation of overpayment were valid and concluded that they were valid. Id. at 342, 347–49. Second, he addressed whether the Part B services provided to the sampled beneficiaries were sufficiently documented and medically reasonable and necessary pursuant to the provisions of §§ 1862(a)(1) and 1833(e) of the Social Security Act. Id. at 342. The ALJ reviewed the services provided to fifteen beneficiaries and found that the ZPIC and the

QIC had incorrectly found nine of the fifteen to be unsupported by documentation of medical necessity. Id. at 377–80. The ALJ required the overpayment to be recalculated considering the partially favorable ALJ decisions on the individually sampled claims. Id. at 375. Third, he considered, if payment could not be allowed, whether the limitation of liability provisions of § 1879 of the Social Security Act apply to GCPM or the beneficiaries. Id. at 342. Fourth and finally, he addressed, if the overpayment assessment was valid, whether GCPM or the beneficiaries are entitled to a waiver under § 1870(b) of the Act. Id. With respect to the third and fourth issues, the ALJ found that the limitation of liability under § 1879 applied to the beneficiary but not to GCPM and further found that GCPM was not without fault and thereby liable for the overpayment pursuant to § 1870. Id.

In other words, the Secretary is correct: the court misstated the holdings of the ALJ Decision when it stated "The ALJ Decision found the statistical sampling and extrapolation of overpayment to be valid but ordered that the overpayment amount be recalculated in light of AdvanceMed's removal of sixteen zero-paid claim lines, which had increased the error rate from 89.5% to 94%." ECF No. 66 at 8. GCPM agrees that the court misstated a non-operative fact. ECF No. 76 at 8. However, it notes that this misstatement "has no effect on the operative facts and legal rationale of either of the Court's Orders." Id. at 9. The court agrees with GCPM. See id. Importantly, the court did not rely on its erroneous interpretation of the ALJ Decision in either the order on the motion to complete the administrative record or the interrelated order imposing sanctions.

Specifically, in the order resolving the motion to complete the administrative record, the court found that the complete administrative record was not before the court.[14] ECF No. 43 at 21–26. "The record is incomplete if it fails to provide a court with all of the documents, memoranda, and other evidence that was considered directly or indirectly by the agency." Tafas v. Dudas, 530 F. Supp. 2d 786, 795 (E.D. Va. 2008). The court found that "GCPM ha[d] provided clear evidence that AdvanceMed and/or Palmetto acted on behalf of the agency and relied on the Universe, the Missing Universe, the Adjusted OP File, and the Adjusted OP File Calculations, which are not currently included in the administrative record before the court." ECF No. 43 at 25. This conclusion has not changed.[15] The court has attached excerpts from the administrative record with the relevant sections highlighted to reiterate its conclusion. See Admin. R. 518, 605.

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[14] 42 C.F.R. § 405.1042(a) is the applicable regulation that guides the creation of the administrative record. Subsection (2) of the regulation provides,

> The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

42 C.F.R. § 405.1042(a)(2).

[15] Indeed, a review of the ALJ Decision shows that the question of whether the universe legally should include zero-paid claims remains an issue preserved for direct appeal before this court, such that the voided zero-paid claims remain a relevant and necessary part of the complete administrative record. Admin. R. 1 at 347–49. The court has attached the relevant excerpt from the ALJ Decision and highlighted the pertinent sections.

Likewise, the court's order resolving the motion for sanctions is also unchanged by the correct interpretation of the ALJ Decision. Perplexingly, the Secretary, in various filings, consistently refers to the voiding of the zero-paid claims as an "affirmative task" for the Medicare program integrity contractor. ECF Nos. 55 at 10 ("[T]he universe is affirmatively defined by the program integrity contractor, as one of the 'major steps' that the MPIM directs the contractor to make in designing an audit"); 58 at 4 ("The applicable audit guidelines direct that the affirmative task of 'defining the universe' for an audit is a step to be taken by the Medicare program integrity contractor at the outset"). At the hearing, the court asked counsel for the Secretary to explain what he meant by "affirmative step." ECF No. 78. He indicated that the first step that the agency takes pursuant to the MPIM is to establish who defines the universe and how the universe is defined. Id. If an agent of the Secretary is taking the "affirmative step" of defining the universe, that body of data from which the universe is defined is a necessary part of the administrative record. See Tafas, 530 F. Supp. 2d at 795. Thus, the Secretary's failure to preserve and produce the universe inclusive of the still-relevant zero-paid claims remains sanctionable. See Diaz-Fonseca v. Puerto Rico, 451 F.3d 13, 26 (1st Cir. 2006). As such, while the court appreciates the clarification as to the ALJ Decision from the Secretary, it does not move the needle on the order granting the motion for sanctions.

B. MPIM § 8.4.3.2.1

The Secretary next avers that the court cited to an incorrect portion of the MPIM which is inapplicable to the composition of the universe in a Medicare Part B audit. ECF No. 73 at 4. The court cited MPIM § 8.4.3.2.1 and specifically quoted from subsection A which impacts Medicare Part A audits, and not subsection B, which provides the standard

for Medicare Part B audits. ECF No. 66 at 4. GCPM argues that, to the extent the Secretary's motion takes issue with the proper definition of the "universe" under the MPIM, this is an improper argument on the merits. ECF No. 76 at 9–10. In reply, the Secretary reiterates that by citing to MPIM § 8.4.3.2.1.A, the court "looked to an incorrect and inapplicable manual guideline on the composition of the Medicare claims universe," and therefore when the proper MPIM provision is considered, "[t]he only 'universe' in this audit was what the auditor, . . . AdvanceMed, defined as the universe." ECF No. 77 at 2. He emphasizes that the court "sanctioned the Secretary on the basis of a mistaken understanding of 'universe,' derived from a manual provision that did not apply." Id. at 3.

At the hearing, the court agreed that it erroneously quoted the incorrect language in the background section of the order. GCPM is a Medicare Part B provider. Amend. Compl. ¶ 4. Thus, the appropriate section of the MPIM governing Part B Claims indicates that "[t]he universe shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed." MPIM § 8.4.3.2.1.B. This change is also reflected in the background section of this order.

However, for many of the same reasons delineated above in the section addressing the court's misstatement of the ALJ Decision, the court finds that its misstatement of the MPIM had no impact on the court's analysis of the motion for sanctions. The Secretary implicitly concedes that this did not matter for the motion for sanctions when he explained "[t]his will matter when the Court considers the merits of

the case." ECF No. 73 at 6.[16] The court also agrees that its misstatement of MPIM § 8.4.3.2.1 did not affect its resolution of either the motion to complete the record or the motion for sanctions.

C. Impermissible Fact-Finding

As a third basis for the motion for reconsideration, the Secretary argues that the order "deviates from the nature and limitations of judicial review authorized in a case of this nature," when the court held certain facts as established. ECF No. 73 at 6. He claims that this case is before the court on the jurisdictional basis of 42 U.S.C. § 1395fff(b), which expressly incorporates the terms of the Social Security Act's review provision at 42 U.S.C. § 405(g). Id. He contends that in cases governed by § 405(g), the reviewing courts are restricted to the administrative record in performing their limited function of determining whether the Secretary's decision is supported by substantial evidence. Id. at 7 (first citing Huckabee v. Richardson, 468 F.2d 1380, 1381 (4th Cir. 1972); and then citing MacKenzie Med. Supply, Inc. v. Leavitt, 506 F.3d 341, 346 (4th Cir. 2007)).

In response, GCPM avers that the court is permitted to engage in fact-finding that is supported by the administrative record or that develops an evidentiary record for constitutional challenges. ECF No. 76 at 10–11. GCPM "solely raises due process challenges to the statistical sampling methodology and extrapolation, which were not adequately considered or decided by the ALJ at the lower level." Id. at 10. Thus, "it is

[16] Confusingly, the Secretary also claims it presently impacts the analysis of the motion for sanctions because "the Court has sanctioned the Secretary for not producing a particular 'universe' file that was never defined and hence never existed, indeed, a file that need never have been defined or brought into existed under the terms of the [MPIM]." ECF No. 73 at 6. While the court has addressed this argument, in part, in its analysis of the ALJ Decision, it provides additional context in its analysis of the Secretary's third identified error.

completely appropriate . . . for this Court to develop an evidentiary record to properly evaluate the merit of those constitutional challenges." Id. at 10–11.

As this court has previously noted, GCPM alleges multiple violations of GCPM's due process rights under the Fifth and Fourteenth Amendments to the United States Constitution, as well as violation of the Social Security Act, 42 U.S.C. § 1395 et seq., and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et seq. Amend. Compl. ¶¶ 257–92. In other words, it is a direct appeal of the final agency decision—the ALJ Decision—and GCPM also brings related constitutional and statutory claims. See id.

Unfortunately, the causes of action in the complaint are confusing. See Amend. Compl. ¶¶ 257–92. For example, GCPM lists Count 1 as "AdvanceMed's failure to Produce the Universe of Claims in its Statistical Sampling Violated Plaintiff's Right to Due Process," rather than listing Count 1 as "Procedural Due Process" with each of the allegations which allegedly gave rise to the constitutional violation(s). See id. ¶¶ 257–66. As a result, the complaint must be meticulously examined to determine which allegations are appeals from the final agency decision versus which allegations are affiliated constitutional claims brought for the first time in federal district court. See Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 15 (2000) (citing Mathews v. Eldridge, 424 U.S. 319, 326–27 (1976)) (explaining that a Medicare appellant's constitutional issue is raised "collateral" to his claim for benefits, though the appellant must first channel its action arising under the Medicare Act through the agency).[17]

[17] To be clear, the appellant must first channel its action arising under the Medicare Act through the agency. Ill. Council on Long Term Care, Inc., 529 U.S. at 23. Both parties agree that GCPM has done so here. See 42 U.S.C. § 405(g), (h); see also Amend. Compl. ¶ 13; ECF No. 73 at 6.

The court starts by reviewing its ability to make factual determinations as to the claims on direct appeal from the agency and thereafter notes its authority to develop a factual record with respect to the collateral constitutional claims that GCPM also brings before the court.

1. Direct Appeal of Agency Final Decision

With respect to the Secretary's arguments as to the direct appeal of final agency action, the court finds that the Secretary misstates the claims that are presently before the court and merely rehashes previous arguments presented to the court. See South Carolina v. United States, 232 F. Supp. 3d 785, 793 (D.S.C. 2017) ("[A] motion to reconsider an interlocutory order should not be used to rehash arguments the court has already considered merely because the movant is displeased with the outcome").

Initially, the court reiterates that it may develop a factual record for those claims that are on direct appeal from the final agency decision. Despite the redundancy with this court's prior orders, the undersigned finds it material to repeat the role of the administrative record and the court's authority to require completion of that record. As a general matter, "claims brought under the APA are adjudicated without a trial or discovery, on the basis of an existing administrative record." Mayor & City Council of Balt. v. Trump, 429 F. Supp. 3d 128, 137 (D. Md. 2019) (quoting Audubon Naturalist Soc'y of the Cent. Atl. States, Inc. v. U.S. Dep't of Transp., 524 F. Supp. 2d 642, 660 (D. Md. 2007)). This "reflects the recognition that further judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided." Dep't of Com. v. New York, 588 U.S. 752, 780–81 (2019) (citation omitted).

"Section 706 of the APA commands the reviewing court to review the 'whole record or those parts of it cited by a party.'" Tafas, 530 F. Supp. 2d at 793 (quoting 5 U.S.C. § 706). "The record is incomplete if it fails to provide a court with all of the documents, memoranda, and other evidence that was considered directly or indirectly by the agency." Id. at 795 (emphasis added). "If an agency fails to produce a complete administrative record, a party may request supplementation of the record." See S.C. Coastal Conservation League, 611 F. Supp. 3d at 141 (internal citations omitted) (emphasis added). The Fourth Circuit succinctly stated the foundation of this principle when it noted that "[i]f judicial review were to be tethered to these abbreviated documents, it would almost inevitably become[] a meaningless gesture and would be reduced to a game of blind man's bluff." Appalachian Power Co. v. EPA, 477 F.2d 495, 507 (4th Cir. 1973), rejected on other grounds by Union Elec. Co. v. EPA, 427 U.S. 246 (1976) (internal quotation marks omitted).

Consequently, "although review is based on a limited record, 'there may be circumstances to justify expanding the record or permitting discovery.'" Fort Sumter Tours, Inc. v. Babbitt, 66 F.3d 1324, 1336 (4th Cir. 1995) (quoting Pub. Power Council v. Johnson, 674 F.2d 791, 793 (9th Cir. 1982)). As such, completion of the administrative record in an APA case is appropriate only in very limited circumstances, such as:

> (i) if it appears that the agency relied on documents or materials not included in the record or if the agency deliberately or negligently excluded documents that may have been adverse to its decision;
>
> (ii) if background information is needed to determine whether the agency considered all the relevant factors, or to permit explanation or clarification of technical terms or subject matter; or
>
> (iii) if the agency so failed to explain administrative action that it frustrates judicial review.

Brandon v. Nat'l Credit Union Ass'n, 115 F. Supp. 3d 678, 684 (E.D. Va. 2015) (citing City of Dania Beach v. FAA, 628 F.3d 581, 590 (D.C. Cir. 2010)); see also Tafas, 530 F. Supp. 2d at 793–95 (collecting cases). Courts must apply the "presumption of regularity"—i.e., the presumption that public officers have properly discharged their official duties—absent clear evidence that those duties were improperly discharged. See United States v. Chem. Found., 272 U.S. 1, 14–15 (1926). Applying that concept to judicial review of agency action, "there is a presumption that the agency properly designated the administrative record, and plaintiffs must show clear evidence to the contrary to obtain discovery." Tafas, 530 F. Supp. 2d at 795; see also Sanitary Bd. of City of Charleston v. Wheeler, 918 F.3d 324, 334 (4th Cir. 2019) (explaining there is a strong presumption that the agency properly designated the full and accurate record).

Nevertheless, the record is not comprised of only those documents that the agency has compiled and submitted as the administrative record. Clinch Coal. v. U.S. Forest Serv., 597 F. Supp. 3d 916, 921 (W.D. Va. 2022). "In other words, the agency 'may not unilaterally determine what constitutes' the record, otherwise there would be no need for a presumption." Id. (quoting Bar MK Ranches v. Yuetter, 994 F.2d 735, 739–40 (9th Cir. 1989)). A party seeking to "complete" the record may overcome that presumption with "clear evidence" that the documents it seeks to add were considered by agency decisionmakers. S.C. Coastal Conservation League, 431 F. Supp. 3d at 723. To make this showing, a party must provide "reasonable, non-speculative grounds for the belief" that documents actually considered by the agency were omitted and identify the pertinent materials "with sufficient specificity, as opposed to merely proffering broad categories of documents and data that are likely to exist." Id.; see also Tafas, 530 F. Supp. 2d at 795

(explaining that clear evidence may be demonstrated by a strong, substantial, or prima facie showing that the record is incomplete).

In its prior order, the court found that GCPM had identified reasonable, non-speculative grounds that documents that were considered by the agency were not included in the administrative record and properly identified the specific excluded records. Moreover, GCPM has provided clear evidence that AdvanceMed and/or Palmetto acted on behalf of the agency and relied on the Universe, the Missing Universe, the Adjusted OP File, and the Adjusted OP File Calculations, which were not included in the administrative record before the court.[18] "To exclude these documents and any similar documents that have yet to be disclosed would, in effect, create an inaccurate record for the court's ultimate review." S.C. Coastal Conservation League, 431 F. Supp. 3d at 723. The Secretary emphasizes that defining the universe is an "affirmative step" that the Secretary must undertake. ECF No. 78. Consequently, the documents and records related to that "affirmative step"—including the data from which the universe is

[18] The court supplements this previous analysis with citation to the ALJ Decision. The ALJ rejected GCPM's argument that it was denied due process because it was unable to replicate the sample because the universe did not include zero-paid claims. Admin. R. 1 at 347–49. The ALJ had previously concluded that the ZPIC complied with the MPIM requirements and appropriately excluded non-paid claims, which is a conclusion he reached with reference to MPIM § 8.4.3.2.1, 8.4.3.2.3. Id. For his due process analysis, the ALJ cited its prior analysis of zero-paid claims and noted that zero-paid, or non-paid claims, are excluded from the universe and therefore "the sampling information provided by the ZPIC appears to be sufficient documentation to recreate the sampling methodology." Id. The court must uphold the Secretary's factual determinations if they are supported by substantial evidence and were reached by applying the correct legal standard. 42 U.S.C. § 405(g); New ex rel. D.J.M. v. Astrue, 374 F. App'x 416, 418 (4th Cir. 2010). The Secretary's legal conclusions are reviewed de novo. New ex rel. D.J.M., 374 F. App'x at 418; see also Joshi v. Garland, 2024 WL 3710511, at *5 (4th Cir. Aug. 8, 2024). Therefore, the issue of the zero-paid claims is properly before the court and requires the court to engage in de novo review.

created—must be included in the administrative record. See Tafas, 530 F. Supp. 2d at 795. Importantly, in this case, the court is not restricted merely to the directly appealed claims because GCPM also brings collateral constitutional claims. See Amend. Compl. ¶¶ 257–93.

2. Collateral Constitutional Claims

Relevant here, the Supreme Court has explained that an appellant's constitutional claim is raised "collateral" to his claim for benefits. Ill. Council on Long Term Care, Inc., 529 U.S. at 15 (citing Mathews, 424 U.S. at 326–27). The Court went on to say that the court reviewing the agency determination under § 405(g) "has adequate authority to resolve any statutory or constitutional contention that the agency does not, or cannot, decide . . . including, where necessary, the authority to develop an evidentiary record." Id. at 23–24.

GCPM raised several claims before the ALJ including its due process claim that it was unable to replicate the sample because the universe did not include zero-paid claims before the ALJ, meaning it properly exhausted that claim. See Admin. R. 1 at 347–49. The court will review the ALJ's legal analysis de novo and review the Secretary's factual determinations under the substantial evidence standard. See Joshi, 2024 WL 3710511, at *5 (citing Garland v. Ming Dai, 593 U.S. 357, 365–66 (2021)). Under the substantial evidence standard, administrative findings of fact are conclusive unless any reasonable adjudicator would be compelled to conclude to the contrary and the court may not reweigh evidence. Id. (citing Nasrallah v. Barr, 590 U.S. 573, 583–84 (2020)). The court previously adopted reasoning from a published Fifth Circuit decision which held that effectuation of final agency decisions is reviewable under § 405(g) as continuous aspects

of the initial, properly exhausted administrative decision. ECF No. 43 at 19; see also D&G Holdings, L.L.C. v. Becerra, 22 F.4th 470, 471–72 (5th Cir. 2022). Thus, the court finds that GCPM properly exhausted its claims related to the recalculation of the overpayment extrapolation, recoupment, and accounting. In other words, GCPM has a final agency decision on its claim for benefits. See Ill. Council on Long Term Care, Inc., 529 U.S. at 15 (citing Mathews, 424 U.S. at 326–27).

GCPM also raises several procedural due process claims that are "collateral" to its claim for benefits and permissibly before the court. See Ill. Council on Long Term Care, Inc., 529 U.S. at 15. For example, it claims that the Secretary's failure to produce the missing universe of claims and the recalculation documentation deprived it of its due process rights to dispute and contest the agency's analysis. See Amend. Compl. ¶¶ 257–66, 273–80. A claimant may seek judicial review, including of constitutional and statutory claims arising under the Medicare Act, only after receiving a final decision from the Secretary. Ill. Council on Long Term Care, Inc., 529 U.S. at 19; see also Row 1 Inc. v. Becerra, 92 F.4th 1138, 1140–42 (D.C. Cir. 2024). GCPM's procedural challenges are "inextricably intertwined" with its claims for Medicare benefits and must be channeled through the agency. See Row 1 Inc., 92 F.4th at 1146 (citing Heckler v. Ringer, 466 U.S. 602, 614 (1984)). The parties agree that GCPM has received a final decision from the Secretary, meaning that GCPM "has followed the special review procedures set forth in § 405(g), thereby complying with, rather than disregarding, the strictures of § 405(h)." See Ill. Council on Long Term Care, Inc., 529 U.S. at 14–15; Mathews, 424 U.S. at 329–30 & n.10 (explaining that § 405(g) requires only that there be a "final decision" by the Secretary with respect to the claim of entitlement to benefits but a party's failure to raise

its constitutional claim before the Secretary would not bar it from asserting it later in a district court); cf. Weinberger v. Salfi, 422 U.S. 749, 764 (1975) (holding that the named class members which sought review of the denial of benefits based on the plain wording of a statute which was alleged to be unconstitutional—a benefit denial based on a statute that the Secretary could not modify or affect—constituted a final decision of the Secretary satisfying the requirements of § 405(g)). Thus, GCPM's collateral constitutional claims are properly before the court to review.

IV. CONCLUSION

For the reasons set forth above, the court **DENIES** the motion for reconsideration.

AND IT IS SO ORDERED.

DAVID C. NORTON
UNITED STATES DISTRICT JUDGE

August 29, 2024
Charleston, South Carolina